K100292

Submitter Name	Pie Medical Imaging BV
Submitter Address	Becanusstraat 13 D; 6216 BX Maastricht, The Netherlands
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Preparation Date	17 March 2010

APR 30 2010

Trade Name	CAAS QxA 3D
Common Name	Cardiovascular Angiography Analysis System CAAS QCA 3D CAAS QVA 3D
Regulation Class	Class II (21 CFR, part 892.2050, LLZ)
Predicate Devices	CAAS, cleared for marketing under K052988 CAAS QCA 3D, cleared for marketing under K063344 IC-Pro, cleared under K083745

Device Description

The CAAS QxA 3D covers the QCA 3D and QVA 3D software modules intended to run on the Cardiovascular Angiography Analysis System (CAAS). The CAAS QxA-3D is designed for objective, accurate and reproducible assessment of the vessel geometry from a set of angiographic X-ray images from different projections. The variant QCA 3D is intended for coronaries and the variant QVA 3D is intended for peripheral vessels.

On each of the 2D images an arterial segment is selected resulting in automatic contour detection. The detected 2D arterial contours in each image are used to generate a 3D reconstruction of the arterial segment. A number of analysis results can be calculated.

1. Vessel dimensions such as area, diameter and length;
2. Reconstruction of healthy vessel shape;
3. User defined subsegments analysis.

Results are corrected for out-of-plane magnification and foreshortening errors. CAAS QxA 3D features a virtual display of an implantable device on the 2D images and assists to plan its position based on the 3D reconstruction.

Intended Use

CAAS QxA 3D is used as follows:

1. 3D Reconstruction of coronary arteries and peripheral vessels from a set of angiographic X-ray images;
2. Calculation of dimensions of the vessel corrected for out-of-plane magnification and foreshortening errors;
3. To determine acquisition parameters for optimal imaging of part of interest on a vessel tree;
4. To assist in the positioning of implantable devices in the vessel segment of interest.

CAAS QxA 3D software is designed for use in clinical practice to support diagnoses and interventional treatment of cardiovascular conditions. The software is used by or under supervision of a cardiologist or radiologist.

Performance Data	CAAS QxA 3D is developed, tested, validated and produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.
Substantial Equivalence	The intended use and technological characteristics of CAAS QxA 3D are substantial equivalent to a combination of the intended use and technological characteristics of the predicate devices.
Conclusion	The testing reported in this 510(k) establishes that CAAS QxA 3D is substantial equivalent to a combination of predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR 30 2010

Mr. Saskia Lloyd
Submission Correspondent-Quality Assurance Officer
Pie Medical Imaging b.v.
Becanusstraat 13D, 6216 BX Maastricht
THE NETHERLANDS

Re: K100292
Trade/Device Name: CAAS QxA 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 30, 2010
Received: April 5, 2010

Dear Mr. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

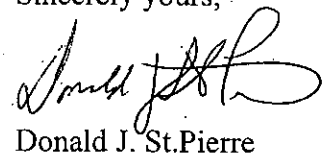
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) number (if known): K100292

Device Name: CAAS QxA 3D

Indications For Use:

CAAS QxA 3D is used for:

1. 3D Reconstruction of coronary arteries and peripheral vessels from a set of angiographic X-ray images;
2. Calculation of dimensions of the vessel corrected for out-of-plane magnification and foreshortening errors;
3. To determine acquisition parameters for optimal imaging of part of interest on a vessel tree;
4. To assist in the positioning of implantable devices in the vessel segment of interest.

The CAAS QxA 3D software is designed for use in clinical practice to support diagnoses and interventional treatment of cardiovascular conditions. The software is used by or under supervision of a cardiologist or radiologist.

Indications for use:
CAAS QCA 3D: coronary arteries
CAAS QVA 3D: peripheral vessels

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A Becker
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100292

(Optional Format 1-2-96)